

Remarks

Claims 2-6, 8-23, and 28 were rejected under 35 U.S.C. 103(a) as being unpatentable by U.S. Publication No. 2002/0168290 ("Yuzhakov") in view of U.S. Patent No. 7,396,334 ("Kuhr"). Claims 2-6, 8-13, 16-17, 21-23 and 27 and new claims 29-30 depend (directly or indirectly) from independent claim 18. Claim 19, which is directed to a device produced by the method of claim 18, is the base claim for the remaining dependent claims 14, 15, 20, and 26.

Regarding independent claim 18, the Official Action asserts that Yuzhakov discloses a method for producing combined puncturing and measuring devices by forming puncturing points on a band-shaped support material. The Official Action further states that Yuzhakov does not disclose sterilizing the puncture points, does not disclose sealing the puncturing points by embedding each point in a soft plastic cover, and does not disclose applying a detection element to the sterilized band-shaped support material. The Official Action states that Kuhr teaches such limitations and that it would be obvious to include that teaching in Yuzhakov to prevent infection.

Quite simply, the teachings of Kuhr regarding the maintenance of sterility are not properly combinable with the puncturing devices of Yuzhakov. Kuhr presents a hard plastic part 5 that has a capillary gap 7 thereon that directs blood to test field 10 positioned on the outside of hard plastic part 5. Internal to hard plastic part 5, elastic material 6 is disposed for receiving a tip of lancet needle 3. Hard plastic part 5 and elastic material 6 combine to encase lancet needle 3. However, test field 10 is not suitable for sterilization. "A sterilization of the disposables after final assembly could result in damage to sensitive chemical or biological substances in the test field. This can be avoided by the process according to the invention." Kuhr Col. 8, ll. 62-64. After sterilization, the combination of hard plastic part 5 and elastic material 6 combine to maintain the sterility of the lancet needle.

Claim 18 requires "applying a detection element to the sterilized [material in which the points are formed]." Clearly, the thin rod-like nature of the lancet needle 3 of Kuhr makes it difficult, if not impossible, to mount a detection element thereon. Accordingly, Applicant assumes that the proposed rejection involves using the support material and lancet points of Yuzhakov and applying the encasing features of Kuhr thereto. In that more than just the tip of lancet needle 3 is expected to engage a patient's anatomy, sterilization of the lancet needle 3

generally is needed. To this end, hard plastic part 5 along with elastic material 6 provides the needed enclosure.

This presents a problem when attempting to combine its teachings with the teachings of Yuzhakov. Notably, at what point is the detection element applied to the support material? Two options are available. 1) before placing the support material in the housing/elastic and 2) after placing the support material in the housing/elastic.

Option 1 is unsuitable because the detection material would be subjected to the sterilization process, and as stated by Kuhr, "A sterilization of the disposables after final assembly could result in damage to sensitive chemical or biological substances in the test field."

Option 2 is also unsuitable because the application of the detection material would require the opening of the housing, thus breaking the seal and allowing contaminants in the sterilized area.

Accordingly, one of skill in the art would not look at the teaching of Kuhr on how to maintain sterility of a sterilized lancet needle and deem it to be readily combinable with a lancet system that requires application of the detection element to the sterilized support material that makes up the lancet needle. Such a combination either fails to allow maintenance of sterility, or fails to allow application of the detection element.

Even more explicitly, claim 19 requires "a detection element which is applied to the individual puncturing/measuring disposable body after the latter has been sterilized and/or sealed." As previously discussed, the combination of Kuhr and Yuzhakov does not allow such a limitation.

If necessary, Applicant requests that this response be considered a request for an extension of time appropriate for the response to be timely filed. Applicant requests that any required fees needed beyond those submitted with this amendment be charged to the account of Baker & Daniels, Deposit Account No. 02-0390.

The Examiner is invited to contact the undersigned at the telephone number provided below should any question or comment arise during consideration of this matter.

Respectfully Submitted,

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